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Pesticide Fact Sheet Number 153: Asulan

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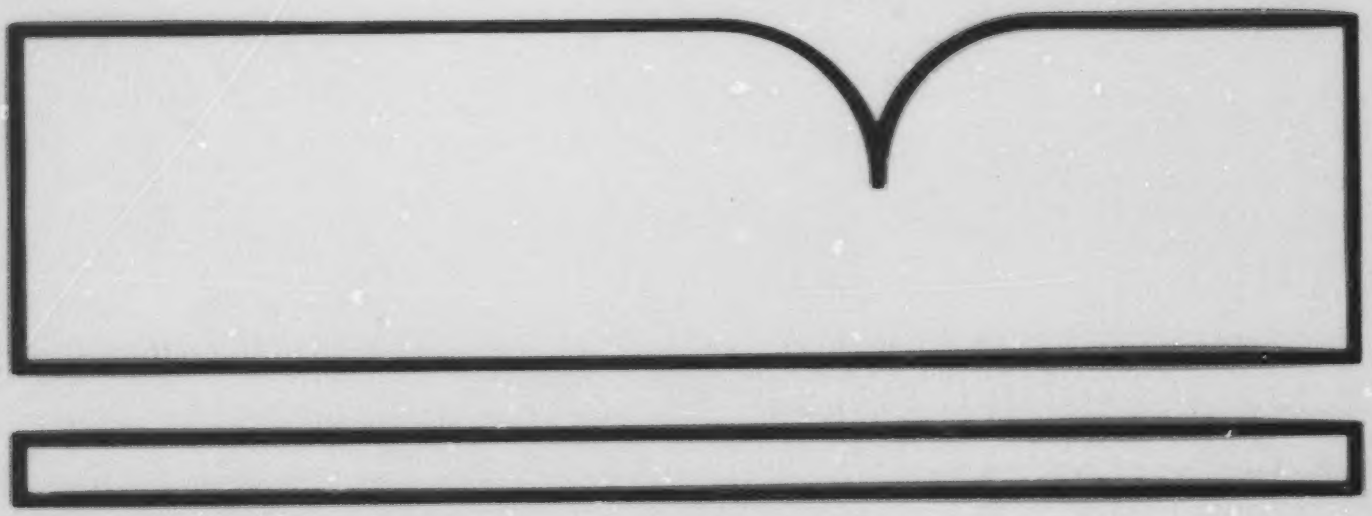

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

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Office of Pesticide Programs (TS-766C)
Washington, DC 20460

EPA

Pesticide Fact Sheet

Name of Chemical: Asulam
Reason for Issuance: Registration Standard
Date Issued: JAN 4 1988
Fact Sheet Number: 153

1. Description of Chemicals

Generic Names: Methyl sulfanilylcarbamate and sodium salt of methyl sulfanilylcarbamate
Common Names: Asulam and sodium salt of asulam
Trade Name: Asulox
EPA Shaughnessy Code: 106901 (asulam)
106902 (sodium salt of asulam)
Chemical Abstracts Service (CAS) Number: 3337-71-1 (asulam)
2302-17-2 (sodium salt of asulam)
Year of Initial Registration: 1975
Pesticide Type: Herbicide
Chemical Family: Carbamate
Producer: Rhone-Poulenc, Inc.

2. Use Patterns and Formulations

Application Sites: Sodium salt of asulam is used for the postemergent control of broadleaf weeds, perennial grasses, and nonflowering plants on sugarcane and noncrop areas (such as rights-of-way), forestry sites (including Christmas tree plantations, site preparation, and conifer release), ornamentals, established turf, and aquatic sites (ditchbanks).

Types of Formulations: 86.4% asulam technical manufacturing-use product; 36.2% end-use product formulated as a soluble concentrate/liquid of the sodium salt of Asulam (equivalent to 3.34 pounds of asulam per gallon).

Types and Methods of Application: Surface and aerial spray and spot treatment.

Application Rates: From 1.67 to 6.68 pounds active ingredient per acre depending upon the use pattern and target weed species.

Usual Carrier: Water.

3. Science Findings

Summary Science Statement: Asulam poses a limited oncogenic risk from dietary and worker exposure. The pesticide is tentatively classified as a Category C carcinogen (limited evidence of carcinogenicity in animals) according to EPA's Guidelines for Carcinogen Risk Assessment on the basis of a rat oncogenicity study which showed a statistically significant increase in benign adrenal gland pheochromocytomas in males at high dose only, and also statistically significant increase in thyroid gland C-cell carcinomas in low- and mid-dose males. Asulam did not produce a compound-related statistically significant increase in tumors in a mouse oncogenicity study. Available mutagenicity data are negative.

Tumors were produced in only one strain and sex of rodent, and in only a single experiment. Because of this rather limited evidence, quantification of human risk is considered inappropriate.

Asulam did not induce teratogenic effects (birth defects) or impair reproductive ability.

Data are insufficient to fully assess the acute toxicity of asulam to humans. However, available data on dermal and eye irritation and sensitization indicate that asulam is not acutely toxic to humans. In addition, data indicate that asulam is not acutely toxic to avian, aquatic, or mammalian species. Available data are insufficient to completely assess the environmental fate of asulam. Residues may carry over to subsequent crops and asulam may possibly contaminate ground water.

Chemical Characteristics:

Color: Cream to buff (technical [T])
White (Pure Grade Active Ingredient [PGAI])

Physical State: Powder (T)
Crystalline (PGAI)

Odor: Slight (T)
None (PGAI)

Melting Point: Approximately 135 °C (T)
(decomposes)
143 to 144 °C (PGAI)
(decomposes)

Solubility: Ethanol - 12.4 g/100 mL
Methanol - 35.6 g/100 mL
Acetone - 38.5 g/100 mL
Methyl ethyl ketone - 34.5 g/100 mL
Dimethyl formamide - > 170 g/100 mL
Water - 0.425 g/100 mL

Octanol/Water
Partition
Coefficient:

0.30 at 0.01 m
0.76 at 0.001 m
1.76 at 0.0001 m

Toxicity Characteristics:

Acute Effects[1/]:

Primary Eye Irritation (Rabbit): Conjunctival irritation cleared by day 7; no observed corneal or iris irritation. Toxicity Category III.

Primary Skin Irritation (Rabbit): No irritation. Toxicity Category IV.

Dermal Sensitization: Negative.

Subchronic Effects:

In a supplemental 6-month study dogs were dosed at 60, 300, and 1500 mg/kg in the diet. Low-dose females and males and females at high dose showed increased thyroid weights. Relative thyroid/body ratio was increased in high-dose males and females and, when compared to controls, high-dose males and females showed lower mean body weight gain. The tentative no-observed-effect level (NOEL) is 60 mg/kg/day. The study may be upgraded if appropriate clinical measurement summary tables and other data are submitted.

Chronic Effects:

A 2-year feeding study in Charles River CD rats at doses of 0, 1000, 5000, and 25,000 ppm showed statistically significant increases in benign adrenal gland pheochromocytomas in high-dose males and also significant increases in thyroid gland C-cell carcinomas in low- and mid-dose males. The systemic NOEL = 36 mg/kg/day (720 ppm) based on thyroid follicular hyperplasia in mid- and high-dose males.

A 18 month oncogenicity study in Carworth CI-1 mice at doses of 0, 1500 and 5000 ppm showed a statistically significant positive trend for undifferentiated sarcoma of the skin and subcutis in males. However, these tumors were not considered compound-related because: 1) they occurred only at the high dose in low incidence (4/46), 2) the incidence was not statistically significant though showed

1/ See 40 CFR 162.10 for discussion of toxicity categories and companion labeling requirements.

a positive trend and 3) a parasitic skin infection was present which could have been related to the occurrence of skin tumors. The Agency is requiring a repeat mouse oncogenicity study since 1) the maximum tolerated dose (MTD) was not achieved, 2) two doses rather than three specified in Guidelines were used, and 3) evidence that the test animals were in poor health demonstrated by chronic kidney inflammation and parastic infection.

Developmental Toxicity:

Rabbits were dosed with 0, 150, 300, and 750 mg/kg/day asulam in the diet. The NOEL was 750 mg/kg/day (highest dose tested). Rats were dosed with 0, 50, 1000, and 1500 mg/kg/day. The NOEL was 1500 mg/kg/day (highest dose tested). Not teratogenic.

Two-Generation Reproduction - Rat:

Charles River CD rats were administered 0, 1000, 5000, and 25,000 ppm asulam in the diet. At 5000 and 25,000 ppm there were fewer live births per litter and also slightly lower fertility index in F_1 parents (second generation). The NOEL for reproductive effects is 1000 ppm. Did not impair reproductive ability.

Mutagenicity:

A cell transformation assay was negative. A provisionally acceptable study was negative for dominant lethal effects.

Physiological and Biochemical Behavior Characteristics:

Foliar Absorption: Applied after emergence, asulam is readily absorbed.

Translocation: Asulam may be taken up either by roots or leaves and moves to other parts of the plant.

Mechanism of Pesticidal Action: In the meristematic regions of plants (the growing points are areas of rapidly dividing cells at the tip of the stem, root, or branch), asulam interferes with the process of cell division and expansion.

Environmental Characteristics:

Available data are insufficient to assess the environmental fate of asulam.

Persistence and Absorption: Asulam appears to be resistant to hydrolysis. It is degraded in soil under aerobic conditions with half-life apparently from one to several days with most of degraded material bound to soil. Under anaerobic (flooded) conditions, the amount of bound residues appears to decrease

and degradation rates decrease.

Leaching: Asulam appears to be mobile to very mobile in sand, loamy soil, loam and clay loam soil. In soil columns both the parent compound and degradates leached and were found as 19 to 88 percent of the applied material in the column leachates.

Crop Rotation: Available data indicate that residues may occur in crops grown in areas treated in prior years with asulam.

Environmental Fate and Surface and Ground Water Contamination Concerns: Ability of asulam residues to carry over to subsequent crops will be fully evaluated when the required crop rotation data are submitted. Asulam may possibly contaminate ground water.

Additional data are required before the Agency can fully assess the potential for ground water contamination.

Ecological Characteristics:

Avian Acute Oral Toxicity (40% formulation): > 4000 mg/kg (mallard duck, partridge, pheasant, and pigeon) (> 1600 mg/kg when adjusted to 100% asulam).

Avian Subacute Dietary Toxicity (60% formulation): > 75,000 ppm (pheasant and mallard duck) (> 45,000 ppm when adjusted to 100% asulam).

Freshwater Fish Acute Toxicity:
Bluegill sunfish (technical): > 180 ppm
Rainbow trout (60% formulation): > 5000 ppm
Channel catfish (60% formulation): > 5000 ppm

Freshwater Invertebrate Acute Toxicity (Daphnia): 27 ppm.

Estuarine and Marine Invertebrate Acute Toxicity:

Fiddler crab: > 100 ppm
Grass shrimp: > 100 ppm

Beneficial Insects Acute Contact Study (Honey Bees): 1.28 percent mortality at 36.26 micrograms per bee.

Available data suggest that asulam is practically nontoxic to birds, warmwater fish, and estuarine/marine species, and relatively nontoxic to honey bees. Asulam is not expected to pose a hazard to nontarget organisms; however, additional data are required to be certain.

4. Tolerance Assessment

Tolerances have been established for residues of asulam in or on the raw agricultural commodity sugarcane at 0.1 ppm (40 CFR 180.360).

No Mexican tolerance or Codex Alimentarius Commission Maximum Residue Limits have been established for residues of asulam. A negligible residue tolerance is in effect in Canada for asulam residues in or on flax.

The Agency is unable to complete a full tolerance reassessment because the available asulam toxicology and residue data do not fully support the established tolerance. There are data gaps for metabolism in animals, residue analytical method, and magnitude of residue in sugarcane.

The acceptable daily intake (ADI) is a way of expressing the amount of a substance that the Agency believes, on the basis of the results of data from animal studies and the application of "safety" or "uncertainty" factors, may safely be ingested by humans without risk of adverse health effects. The ADI is expressed in terms of milligrams (mg) of the substance per kilogram (kg) of body weight per day (mg/kg/day).

The Agency has calculated a provisional acceptable daily intake (PADI) of 0.05 mg/kg/day for asulam on the basis of missing data and on a 2-generation reproductive effects study with a reproductive NOEL of 50 mg/kg/day (1000 ppm) but no NOEL for systemic effects and a 1000-fold safety factor.

The established tolerances for asulam have a theoretical maximum residue contribution (TMRC) of 0.0001837 mg/kg/day, which utilizes 0.3673 percent of the PADI.

5. Summary of Regulatory Position and Rationale

Special Review Status: EPA will not place asulam into Special Review because none of the risk criteria for initiating Special Review has been met.

Registration of New Uses of Asulam: The Agency will issue registrations for substantially similar asulam products. However, new uses will be approved only on a case-by-case basis after considering the effects on the TMRC, the MPI (Maximum Permissible Intake), and the oncogenic risks.

Unique Label Precautionary Statements:

End-Use Products

ENVIRONMENTAL HAZARDS

Do not apply directly to water or wetlands (swamps, bogs, lagoons, marshes, or potholes). Do not clean equipment or dispose of equipment washwater in a manner that will contaminate water resources.

CROP ROTATION STATEMENT

Do not rotate with any crop which is not registered for use with Asulam for one year following the last application of this chemical.

CROP USE STATEMENTS

Do not treat sugarcane within 90 days of harvest. Do not graze or feed sugarcane forage and fodder to livestock.

6. Summary of Major Data Gaps (Data Required and Due Date)

Product Chemistry	
(All)	August 1988 and February 1989
Residue Chemistry	
Animal Metabolism	August 1989
Residue Analytical Methods	August 1989
Magnitude of Residues	August 1989 and February 1990
Environmental Fate	
Hydrolysis	November 1988
Photodegradation (water, soil)	November 1988
Aerobic and Anaerobic Soil Metabolism	May 1990
Aerobic and Anaerobic Aquatic Metabolism	May 1990
Leaching and Adsorption/Desorption	February 1989
Small-Scale Prospective Field Leaching Study	May 1988**
Field Dissipation (aquatic sediment and forestry)	May 1990
Rotational Crops (confined and field)	May 1991 and April 1992
Irrigated Crops	May 1991
Toxicology	
Acute Toxicity	November 1988
Subchronic Toxicity (21-day dermal)	February 1989
Mutagenicity (Ames test and chromosomal aberration)	November 1988 and February 1989
General Metabolism	February 1990
Oncogenicity (mouse)	April 1992

**Date protocols are due. After acceptance, the Agency will provide timeframes for submission of the reports.

Ecological Effects	
Freshwater Fish LC_{50} (coldwater fish)	November 1988
Acute LC_{50} Estuarine and Marine Organisms (oyster study)	November 1988
Acute LC_{50} Freshwater Invertebrates	February 1989

7. Contact Person at EPA

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for information purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.